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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,573	09/03/2004	Keisuke Suzuki	023312-0115	1362

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EXAMINER	
SAUCIER, SANDRA E	
ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
05/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/506,573	SUZUKI ET AL.	
	Examiner	Art Unit	
	Sandra Saucier	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 12* is/are rejected.

7)☒ Claim(s) *11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-12 are pending and are considered on the merits.

Claim Rejections - 35 USC § 102

Claims 9, 10, 12 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Guanti *et al.* [A2].

The claims are directed to a process for making an optically active allene of formula (1) comprising reacting the allene of formula (2) with porcine pancreatic lipase and water.

The reference is relied upon as explained below.

Guanti *et al.* disclose the conversion of a substrate of formula (2) [46] with PPL to an optically active monoacetate allene of formula (1), page 1546.

Claim Rejections - 35 USC § 103

Claims 1-3, 5-10, 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guanti *et al.* [A2] in view of Langrand *et al.* [U].

The claims are directed, in the alternative, to an acylation scheme for the resolution of the compound of formula 2.

Guanti *et al.* teach the resolution of the compound of formula 2 by enantioselective hydrolysis of the racemic ester.

Langrand *et al.* teach the resolution of racemic alcohols may be by enantioselective hydrolysis of the racemic ester or enantioselective acylation of the racemic alcohol.

The substitution of the resolution scheme of hydrolysis as taught by Guanti *et al.* for the resolution scheme of acylation as taught by Langrand *et al.* would have been obvious because Langrand *et al.* teach that racemic alcohols

may be resolved by either hydrolysis or acylation using the same enzyme as the reactions catalyzed by lipases are reversible.

Claim 7 is directed to the process described above where R2 or R3 are different and are selected from the group consisting of H, C 1-4 alkyl or C 6-8 aryl.

Guanti *et al.* disclose the substrate of formula 2 where R2 is H and R3 is C5 alkyl.

The substitution of R3 C5 alkyl for a C1-4 alkyl or C6-8 aryl would have been obvious because this substitution is far from the site of catalysis and in the absence of evidence to the contrary, the substitution of alkyl or aryl groups of different lengths on the same substrate (homologs) would have been obvious in view of their structural similarity.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Guanti *et al.* [A2] and Langrand *et al.* [U] as applied to claims 1-3, 5-8 above, and further in view of Wang *et al.* [V].

The claims are further directed to the use of a vinyl ester as the acylation reagent.

Wang *et al.* teach the reversibility of reactions catalyzed by hydrolytic enzymes and that use of a vinyl ester promotes completion of the reaction due to the irreversible nature of the acylation reaction due to the special characteristics of the vinyl ester acylation reaction (page 7201).

One of ordinary skill in the art would have been motivated at the time of invention to make this substitution of enantioselective schemes and choice of an irreversible acylation reagent in order to obtain the resulting compound as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art

as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Response to Arguments

Applicant's arguments filed 4/3/07 have been fully considered but they are not fully persuasive.

Applicant argues that Guanti *et al.* do not teach the enantioselective acylation of allene and that Guanti *et al.* cannot be held to be anticipatory over the amended claims. This is persuasive and the anticipatory rejection of the claims limited to an acylation reaction over Guanti *et al.* has been removed.

Applicant argues that there is no motivation to combine Guanti *et al.* and Langrand *et al.*. This is not persuasive because Langrand *et al.* is a review concerning enzymatically catalyzed strategies for alcohol resolution. The instant optically active allene of formula (2) is an alcohol since R1 is stipulated to be hydrogen. It is well known in the art in the absence of the evidence of criticality or unexpected results to employ lipase catalyzed enantioselective reactions in either direction, that is acylation or hydrolysis, at will, in order to resolve enantiomers of alcohols. This is the teaching of Langrand *et al.*. The critical element which is not fully predictable is which lipase or hydrolase will function to perform this selection. The enantioselectivity is a function of the enzyme employed and the source thereof.

Applicants imply that the asymmetrization of an allene should somehow be different from the asymmetrization of menthol; however, it is the alcohol group which is acylated, just as in Langrand *et al.* which use menthol as the exemplary alcohol, not the allene moiety which is being acylated. Once the lipase which possesses asymmetric activity toward a compound is taught, that particular lipase may be used for that particular compound in either an acylation or hydrolysis scheme for the resolution of enantiomers of that compound. Since Guranti *et al.* has shown that porcine pancreatic lipase, which is a specific enzyme derived from a specific source as the desired asymmetric

activity when use in a hydrolysis scheme, since lipase reactions are reversible, the use of the same PPL in the reverse or acylation process is obvious.

Applicants argue that the structures of the instant allene and menthol are dissimilar and that one could not expect to cross-substitute one chemical reaction for the other. However, the reversibility of acylation/hydrolysis reaction is a function of the lipase enzyme, see Wang *et al.* [V] top of page 7201, not the compound.

Allowable Subject Matter

Claim 11 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The examiner apologizes for the error made in stating that claims limited to the use of porcine pancreatic lipase would be allowable. Clearly PPL was employed in the prior art method of Guanti *et al.* Porcine liver esterase was meant to be indicated.

Claims limited to use of lipase isolated from *Candida antarctica* or *Pseudomonas fluorescens* or *Pseudomonas cepacia* or porcine liver esterase or *Candida rugosa* might be allowable upon presentation. ***Please note italization*** in the names of microbes.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

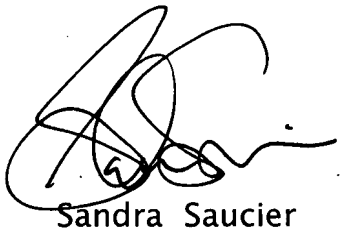
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on

the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sandra Saucier
Primary Examiner
Art Unit 1651
May 17, 2007